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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/184,043 11/02/98 HORNAUER

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AREN'T FOX KINTNER PLOTKIN & KAHN PLLC  
1050 CONNECTICUT AVENUE, N.W.  
SUITE 600  
WASHINGTON DC 20036-5339

EXAMINER

CEPERLEY, M

ART UNIT	PAPER NUMBER
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1641

*14*

DATE MAILED:

02/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/184,043	HORNAUER ET AL.	
	Examiner Mary E. Ceperley	Art Unit 1641	

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

1) Responsive to communication(s) filed on 22 November 2000.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-7,11,14-26,28-38 and 41-50 is/are pending in the application.

4a) Of the above claim(s) 1-7,14-26,28-38 and 41-50 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 11 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some \* c) None of the CERTIFIED copies of the priority documents have been:

1. received.

2. received in Application No. (Series Code / Serial Number) \_\_\_\_\_ .

3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

14) <input type="checkbox"/> Notice of References Cited (PTO-892)	17) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
15) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	18) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
16) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	19) <input type="checkbox"/> Other: _____

Art Unit: 1641

1. Newly presented claims 42-50 have been renumbered as 43-51 in accordance with 37 CFR 1.126. Claim 42 was submitted in the Preliminary Amendment of January 22, 1999.
2. Newly submitted claims 43-50 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 43-50 are drawn to the use of a "modified solid phase reactant which is coupled to a poly(C2-C3)-alkylene oxide". The "solid phase reactant" is defined at page 4 of the specification as "a biomolecule which can specifically interact with an analyte to be determined". Claim 11 (corresponding to elected Group II), on the other hand, is directed to the use of a "conjugate" of the formula (Ia) or (Ib) wherein "P" is "a partner of a high affinity binding pair". "A partner of a high affinity binding pair" is defined at page 6 of the specification as being "a hapten, biotin or a biotin derivative". Thus, the PEG conjugate of claims 43-50 contains a moiety which reacts with the analyte while the PEG conjugate of claim 11 contains a moiety which is used to bind the conjugate to the solid phase. Thus, the two PEG conjugates operate differently in the methods of claims 11 and 42.
3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 43-50 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Art Unit: 1641

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no written description in the specification of the term “inert biomolecule” used to define “I” of formula (Ia) of this claim. See the last Office action, paragraph 3.a).

7. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

a. Steps (a) through (c) which define *a method of detecting an analyte* fail to include/define the steps which would be required to effect “*reducing the unspecific binding to a solid phase*” which is required by the claim preamble.

Art Unit: 1641

b. Claim 11, step (a) fails to recite that the “conjugate” is immobilized on the solid phase via a specific binding interaction of the “P” moiety with its corresponding specific binding pair member which is immobilized on the solid phase (specification, page 7).

c. Claim 11, step (a) fails to recite that the “solid phase reactant” is “analyte-specific” (specification, page 4). This limitation is necessary in order to differentiate the binding specificities of the “conjugate” and the “solid phase reactant”.

8. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what is meant by the term “I is an inert biomolecule”. It is unclear what nature/type of “biomolecule” is required and relative to what type of reaction the biomolecule is “inert”.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Art Unit: 1641

10. Claim 11 is rejected under 35 U.S.C. 102(b)/(e) as being anticipated by each of a) Sluka et al (U.S. 5,932,296), b) Herron et al (U.S. 5,677,196), c) Herron et al (U.S. 5,512,492) or d) Reichert et al (U.S. 5,832,165).

Each of the references describes and therefore anticipates the instantly claimed method of immobilizing two separate moieties to a solid phase and using this solid phase for an immunoassay for an analyte in a sample, the two moieties comprising: (1) a PEG-specific binding member (i.e. biotin) conjugate and (2) a specific binding member which reacts with an analyte. Each of the references also specifically describes the reason for the use of the PEG conjugate i.e. to reduce non-specific binding in the immunoassay as in the instantly claimed method.

See:

- a) Sluka et al: col. 1, lines 35-39; col. 4, lines 3-7, 14-63, in particular lines 38-42;
- b) Herron et al ('196): col. 18, lines 21-29 and 39-44;
- c) Herron et al ('492): col. 2, line 50 – col. 3, line 9; col. 4, lines 2-5; claims 1, 17 and 24;
- d) Reichert et al: col. 13, line 66 – col. 14, line 2; col. 14, lines 11-24; col. 14, lines 58-60; col. 15, line 60 – col. 16, line 3.

Art Unit: 1641

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

*Mary E. Ceperley*  
Mary E. Ceperley  
Primary Examiner  
Art Unit 1641